

REMARKS

AMENDMENT TO THE CLAIMS

Claim 1 is amended herein to limit the impregnated salts to those having a particle size of from 10 $\mu$ m to 2000 $\mu$ m. Support for this amendment is found on page 5, lines 14-18, of the specification.

REJECTIONS UNDER 35 USC §103(A)

Applicants again respectfully submit that the present claims are not obvious over van Ooijen (EP 0 608 975 A1), Gonthier et al. (US 3,600,198), or Kotani et al. (US 4,122,187). The present claims are drawn to impregnated salts of a defined particle size containing a defined proportion of a liquid carboxylic acid. Impregnated salts are produced by the process of impregnation, which is described in the specification. Impregnation entails producing a solid carboxylic acid salt and applying at least one liquid carboxylic acid in such a way as to allow the liquid carboxylic acid to penetrate the crystals of the carboxylic acid salt (p.4:11-15).

Thus, the following elements are necessarily present in the amended claims. There must be at least one solid carboxylic acid salt; from 0.5 to 30%, by weight, of a liquid carboxylic acid must be added to this solid carboxylic acid salt; the particle size of the resulting impregnated salt must be from 10 $\mu$ m to 2000 $\mu$ m. Impregnation is a process that is differentiated from admixing, as may be seen in the disclosure of van Ooijen (p.3:10-15), in that in impregnation, a liquid is introduced into the solid crystalline structure of a salt, whereas in the admixture, two crystalline solids are "intimately mixed"

BROECKEL et al., Serial No.09/487,000

(*id.*). A similar process for producing an admixture is found in Kotani, where the solid sorbic acid is first dissolved in heated ethanol, to which is added either an equimolar amount of potassium sorbate or 0.5 mole of potassium hydroxide per mole of dissolved sorbic acid (col.2:52-64). The mixture is then cooled, and in either variation of this process, the end result is a co-crystalline structure of two solids, as "intimately mixed" as might be possible. An admixture is not an impregnated salt, as one of skill in the art would readily recognize.

VAN OOIJEN, ET AL. (EP 0 608 975 A1)

In addition to the above discussion, which will be applied to van Ooijen below, at least one additional point must be made. The presently claimed invention allows production of a stable composition of a carboxylic acid salt having reduced odor, yet giving a greater percentage of active ingredient upon dispersal than that described in van Ooijen. In the composition disclosed in van Ooijen, equimolar amounts of a carboxylic acid and a hydroxycarboxylate salt are combined. The hydroxycarboxylate salt is a salt of the desired active ingredient, and the carboxylic acid is *of necessity* a different substance. Not only is the carboxylic acid different from the desired active ingredient, but it is also bound by the alkali(ne earth) metal ion dissociated from the hydroxycarboxylate upon dispersion in a solvent.

Thus, the amount of active ingredient able to be released into the solvent is, at a maximum, only *half* of the entire amount of the dissolved composition. For instance, in the single example of van Ooijen, an effective amount of 5.11g of lactic acid, in the form

BROECKEL et al., Serial No.09/487,000

of 6.7g (1 mol water) calcium lactate was mixed with 3.3 g fumaric acid and dissolved in 100ml water. The yield of lactic acid from calcium lactate is reported to be over 94%, i.e., 4.76 and 4.86 in the two iterations, and yet this yield of lactic acid is only approximately 56% of the total weight of the calcium lactate/fumaric acid mixture. 44% of the mixture is, at best, an inert filler which serves to guarantee release of the lactic acid. In practical application, the presence of this additional component reduces the efficiency of total weight to active ingredient conversion, and may disrupt certain processes or require additional steps to remove the resulting carboxylate salt (van Ooijen, p.2:37-44). In other words, only approximately half of any optimal van Ooijen mixture is active ingredient, as the carboxylic acid serves to sequester the alkali(ne earth) metal ions, becoming no more than an inert support or filler, and its presence may introduce unnecessary complications. The conception of van Ooijen's invention as "a method of storing and using hydroxycarboxylic acids ... releasably bound on a support" underscores the extent to which the resulting carboxylate becomes an inert and possibly troublesome ingredient (*id.*, p.2:1-2).

Further, the preferability of from 40-60% carboxylic acid is vital to the efficient performance of the product. The mechanism of action described in van Ooijen requires that the carboxylic acid combine with the alkali(ne earth) metal ion released from the hydroxycarboxylate salt (*id.*, p.2:26-32). This ensures that the hydroxycarboxylic acid released will not revert to its salt form (*ibid.*). If a higher percentage of carboxylic acid is included in the composition, a higher *yield* of hydroxycarboxylic acid may result, as all alkali(ne earth) metal ions will be bound by the excess of carboxylic acid, and yet the

BROECKEL et al., Serial No.09/487,000

overall *amount* of hydroxycarboxylic acid produced per unit of weight of the mixture will be less. Similarly, if a lower percentage of carboxylic acid is included in the composition, the hydroxycarboxylic acid yield will be lower, depending on the reaction conditions, as less carboxylic acid will be available to bind the released alkali(ne earth) metal ions. In this latter case there may be more hydroxycarboxylic acid theoretically available in the composition, and yet its release would be dependent on reaction conditions, rather than 'guaranteed' through the presence of the ion-binding acid having a lower pKa.

Whether the proportion of carboxylic acid is higher or lower than 40-60%, the effectiveness and efficiency of release of the hydroxycarboxylic acid is lowered. Accordingly, even though van Ooijen discloses a theoretical carboxylic acid range of from 1 to 90%, one of skill in the art would recognize that the invention described therein is only effective where the actual range is significantly more narrow, approaching 50%. Given the similarities in molecular weights between the acids and salts described in van Ooijen, it is not likely that an equimolar amount of any contemplated carboxylic acid would be outside the range of 40 to 60% by weight. Accordingly, there is no reasonable expectation for success in employing the carboxylic acid in amounts between 0.5 and 30% by weight. Rather, such a composition would result in lower yields and/or less predictability in producing a desired amount of a hydroxycarboxylic acid. No individual of ordinary skill in the art would be motivated by the van Ooijen disclosure to produce a carboxylic acid/alkali(ne earth) metal hydroxycarboxylate salt mixture in the proportions required by the present claims. Such

BROECKEL et al., Serial No.09/487,000

a mixture would not produce the predictability and yield reported and sought by van Ooijen.

Van Ooijen, does not therefore, disclose that the range of carboxylic acid in an impregnated hydroxycarboxylate salt should be restricted to from 0.5 to 30% by weight. The range disclosed in van Ooijen is from 1 to 90% by weight, with a preference for from 40 to 60% by weight, and a stated optimum where an equimolar amount of a carboxylic acid is impregnated into a hydroxycarboxylate salt. Van Ooijen does not mention an upper boundary of 30%, but through discussion of the mechanism of action and preferred ranges, indicates that such an amount would be inefficient for storing hydroxycarboxylic acids in a releasably-bound state.

Further, van Ooijen does not disclose any specific particle size. The present invention shows that such a particle size restriction improves the storage, flow, and processing properties of the impregnated salt.

For the above reasons, applicants respectfully request that the rejection of claims 1, 2, 4-19, and 21-22 under 35 USC §103(a) based on van Ooijen (EP 0 608 975 A1) be withdrawn.

GONTHIER ET AL. (US 3,600,198)

The Gonthier, et al. reference, likewise, does not teach or suggest an impregnated salt of a carboxylic acid. The examiner has pointed to no clear, express statement in the Gonthier reference indicating that a carboxylate salt is impregnated with a liquid carboxylic acid. If the examiner is relying on an argument of inherency, i.e.,

BROECKEL et al., Serial No.09/487,000

that an impregnated carboxylic acid salt is *necessarily* present in Gonthier, there has been no showing of objective evidence or reasons as to why one of skill in the art would agree that an impregnated carboxylic acid salt is *required* by or *necessarily present* in that disclosure. Gonthier discloses

ice or an aqueous solution containing a mixture of propionic acid and benzoic acid buffered to a pH less than 7 by adding to the acids their corresponding salts of alkali metals or magnesium ...

a mixture of propionic acid and benzoic acid buffered with their corresponding salts of alkali metals or of magnesium ...

mixtures of a buffered mixture of propionic acid/metal propionate and of a buffered mixture of benzoic acid/metal benzoate the total pH of which is lower than 7 and preferably between 4 and 5 ...

propionic acid-sodium propionate and benzoic acid-sodium benzoate; propionic acid-magnesium propionate and benzoic acid-sodium benzoate; propionic acid-sodium propionate and benzoic acid-magnesium benzoate; and propionic acid-magnesium propionate and benzoic acid-magnesium benzoate ...

water to which had been added 2 g./l. of a mixture A having 95 parts (*by volume*) of the buffered propionic acid/sodium propionate of pH 4.5 and 5 parts (*by volume*) of the buffered benzoic acid/sodium benzoate of pH 4.5 ...

2 other germicidal ices from a 2 g./l. aqueous solution, containing either the buffered mixture (B): propionic acid/sodium propionate of pH 4.5 or the buffered mixture (C): benzoic acid/sodium benzoate of pH 4.5 ...

aqueous solutions containing 2 g./l. of ... D: buffered system: propionic acid-sodium propionate at pH 4.5 ... E: propionic acid/sodium propionate plus benzoic acid-sodium benzoate with pH 4.5; the ratio *by volume* of the two constituents being 70/30 ...

aqueous solutions containing 50 g./l. of the products D and E ...

aqueous solutions containing 2 g./l. of the following products (pH=4.5): ... F: propionic acid-magnesium propionate ... G: 95 parts (*volume*) of the buffered: propionic acid-magnesium propionate and 5 parts of the buffered: benzoic acid-sodium benzoate ...H: 50 parts (*volume*) of the buffered: propionic acid-

BROECKEL et al., Serial No.09/487,000

magnesium propionate and 50 parts of the buffered: benzoic acid-sodium benzoate ...

buffered *solution*: propionic acid-Mg propionate. (col.1:14-18, 49-51, 53-56, 58-63, col.3:10-14, 16-19, 62-69, col.4:3-4, col.4:17-26, 46, emphasis supplied).

It is not clear from these disclosures *where*, in particular, Gonthier discloses the *necessary* existence of a carboxylate salt impregnated with from 0.5 to 30% of a liquid carboxylic acid. It is further unclear where Gonthier suggests producing an impregnated salt over, for instance, an admixture or a solution. It is clear from the emphasized phrases above that the mixture employed in 2 g./l. increments is also seen as having a *volume* measurement.

From the Gonthier disclosure it is evident that aqueous solutions containing propionic and benzoic acids and their salts are produced. It is not evident, however, that an impregnated carboxylic acid salt was ever produced or even contemplated therein. As stated by the Federal Circuit,

To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."

(*In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949,1950-51 (1999).) Unless the examiner can set forward extrinsic evidence or rationale showing the existence of an impregnated carboxylate salt according to the present claims, the rejection based on Gonthier is fatally incomplete. Accordingly, applicants respectfully request that the rejection under 35 USC §103(a) based on Gonthier be withdrawn.

BROECKEL et al., Serial No.09/487,000

KOTANI ET AL. (US 4,122,187)

As indicated above, the present claims are drawn to carboxylate salts impregnated with from 0.5 to 30% of a liquid carboxylic acid. Kotani discloses sorbic acid compositions including "double salts" of sorbic acid with sodium or potassium sorbate or with sodium or potassium salts of organic or inorganic acids (col.2:42-52). Sorbic acid is a solid at normal processing temperatures and cannot, therefore, be a liquid carboxylic acid impregnated into the sorbate, organic, or inorganic salts. Again, if the examiner is arguing that an impregnated salt is *necessarily* present in this disclosure, or that the characteristics of an impregnated salt are *necessarily* present in the disclosed double salts of Kotani, the burden remains on the examiner to establish this point.

The sorbic acid in Kotani is heated and dissolved in ethanol, combined with potassium sorbate under heat, and this mixture is then cooled. The examiner has not established that the resulting co-crystalline compound *necessarily* possesses the characteristics of an impregnated carboxylate salt as presently claimed, or that one of skill in the art would recognize this to be the case. Without adequate rationale and/or objective evidence, the examiner's rejection is incomplete. Applicants respectfully request that the rejection based on Kotani et al. be withdrawn.

#### CONCLUSION

In view of the foregoing amendments and remarks, applicants consider that the rejections of record have been obviated and respectfully solicit passage of the

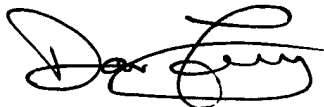


BROECKEL et al., Serial No.09/487,000

application to issue.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,  
KEIL & WEINKAUF

A handwritten signature in black ink, appearing to read 'David C. Liechty', written over a horizontal line.

David C. Liechty  
Reg. No. 48,692

1350 Connecticut Ave., N.W.  
Washington, D.C. 20036  
(202)659-0100

DCL/lc